UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

BRIANNA ROSE,	}
	} **COMPLAINT AND JURY DEMAND**
Plaintiff	}
	} **Civil Action No: 3:17-cv-1077**
	}
-against-	}
	}
ABBOTT LABORATORIES and ABBVIE INC.,	}
	}
Defendants	}

COMPLAINT

Plaintiff, by her attorneys, **SCHLICHTER BOGARD & DENTON** and **DOUGLAS & LONDON, P.C.** on behalf of herself individually, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

2. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391 as Defendants' principal place of business is in this District.

3. This Court has personal jurisdiction over Defendants as their principal headquarters are also in Illinois. Further, Defendants actively advertise, promote, market, sell, and distribute the drug Depakote to physicians and consumers in this state on a regular and consistent basis.

NATURE OF THE CASE

4. This action is brought on behalf of Plaintiff, BRIANNA ROSE, who was exposed to Depakote in utero. Plaintiff BRIANNA ROSE's mother ingested Depakote, which was manufactured, marketed and distributed by Defendants.

PARTY PLAINTIFF

5. Plaintiff, BRIANNA ROSE, is a citizen of the United States of America, and is a resident of the State of Ohio.

6. Plaintiff, BRIANNA ROSE, was born on October 9, 1997.

7. As a result of Plaintiff's in utero exposure to Depakote, Plaintiff BRIANNA ROSE, was caused to suffer from significant cognitive/behavioral impairments.

8. The injuries and damages sustained by Plaintiff, BRIANNA ROSE, were caused by Defendants' Depakote.

PARTY DEFENDANTS

9. Upon information and belief, Defendant ABBOTT LABORATORIES is a Delaware corporation with its principal place of business in Illinois.

10. Upon information and belief, Defendant, ABBOTT LABORATORIES has transacted and conducted business in the State of Illinois and the State of Ohio.

11. Upon information and belief, Defendant, ABBOTT LABORATORIES has derived substantial revenue from goods and products used in the State of Illinois and the State of Ohio.

12. Upon information and belief, Defendant, ABBOTT LABORATORIES expected or should have expected its acts to have consequence within Illinois and Ohio, and derived

substantial revenue from interstate commerce within the United States and the State of Illinois and the State of Ohio, more particularly.

13. Upon information and belief, and at all relevant times, Defendant, ABBOTT LABORATORIES was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Depakote for the treatment of seizures.

14. Upon information and belief, Defendant ABBVIE INC. is a Delaware corporation with its principal place of business in Illinois.

15. Defendant ABBVIE INC. is described on ABBOTT LABORATORIES website as a new, independent biopharmaceutical company composed of ABBOTT LABORATORIES former proprietary pharmaceutical business. On information and belief, ABBVIE INC. is the successor in interest to one or more divisions of ABBOTT LABORATORIES that were in existence prior to its incorporation.

16. ABBVIE INC. was incorporated on April 10, 2012, and began operations as the owner and operator of ABBOTT LABORATORIES proprietary pharmaceutical business in January of 2013.

17. Upon information and belief, Defendant, ABBVIE INC. has transacted and conducted business in the State of Illinois and the State of Ohio.

18. Upon information and belief, Defendant, ABBVIE INC. has derived substantial revenue from goods and products used in the State of Illinois and the State of Ohio.

19. Upon information and belief, Defendant, ABBVIE INC. expected or should have expected its acts to have consequence within Illinois and Ohio, and derived substantial revenue from interstate commerce within the United States and the State of Illinois and the State of Ohio, more particularly.

20. Upon information and belief, and at all relevant times, Defendant, ABBVIE INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Depakote for the treatment of seizures.

FACTUAL BACKGROUND

21. Defendants manufacture, market, and distribute medications containing the active ingredient valproate, valproic acid, and valproate sodium as prescription name brand pharmaceutical products.

22. Defendants first introduced Depakene, an immediate-release formulation of valproate, to the United States market in 1978 for the treatment of seizures.

23. Defendants subsequently introduced Depakote, an enteric coated, stable coordination complex of valproic acid and valproate sodium, to the United States market in 1983 for the treatment of seizures. Depakote was later approved for the additional indications of bipolar disorder and migraines.

24. Defendants subsequently introduced several other strengths and formulations of valproate, valproic acid, and valproate sodium [hereinafter referred to as "valproate"] over the ensuing decades under the brand names Depakene and Depakote, and held the New Drug Applications ["NDAs"] for all dosages and formulations of Depakene and Depakote until at least 2013.

25. On or about January of 2013, Defendant Abbott Laboratories transferred ownership of most or all of the Depakene and Depakote NDAs to Defendant Abbvie.

26. Valproate is a human teratogen, which is an agent that causes birth defects.

27. Defendants knew or should have known that valproate was a human teratogen and should not be prescribed to pregnant women, or women of childbearing years who are likely to become pregnant.

28. In fact, the first report of valproate teratogenicity was published in the medical literature in 1980, within two years of the initial introduction of valproate to the market.

29. In 1982, the association between valproate and neural tube defects was first documented. By 1983, a twenty-fold increase in the rate of spina bifida among infants exposed to valproate during fetal development was reported in the medical literature.

30. In 1984, "fetal valproate syndrome" became a defined term in the medical literature. Defects associated with fetal valproate syndrome include characteristic facial features, major malformations, learning disabilities and central nervous system dysfunction, among other disorders.

31. In particular, the occurrence of neural tube defects (such as spina bifida) from fetal exposure to valproate is estimated to be as high as 5% of all births, compared to approximately 0.1% in the general population.

32. Other congenital defects characteristic of exposure to valproate during early pregnancy include cleft palates, cardiac defects, hypospadias and skeletal abnormalities.

33. Craniofacial abnormalities caused by valproate exposure in utero include such features as trigonocephaly (triangular shaped head due to premature fusion of metopic suture), a tall forehead with bilateral narrowing, flat nasal bridge, broad nasal root, anteverted nostrils, small jaw, abnormalities of the lip and philtrum, epicanthic folds, and midface hypoplasia.

34. Skeletal defects caused by valproate exposure in utero include radial ray and tibial ray defects (deformation of bones in forearm and lower leg), multiple, missing, overlapping, or deformed fingers and toes, extremely elongated fingers or toes, as well as talipes equinovarus (club foot).

35. Abnormalities of the eyes caused by valproate exposure in utero include such defects as bilateral congenital cataract, optic nerve hypoplasia and other defects of the iris and cornea.

36. Congenital heart defects caused by valproate exposure in utero include such defects as ventricular septal defects, aortic and/or pulmonary stenosis, coarctation of the aorta, and atrial septal defect.

37. Defendants knew or should have known that women would ingest valproate as prescribed - on a daily basis – for chronic conditions, and therefore would be exposed to valproate throughout pregnancy.

38. Many other drugs are approved for treatment of seizure disorders, bipolar disorder, and migraine, which present a lower risk of teratogenicity than valproate.

39. Valproate increases the risk of fetal malformation compared to other anti-seizure medications, as well as other medications for the treatment of bipolar disorder and migraine to a statistically significant degree.

40. Valproate also increases the risk of fetal malformations compared to no use of medications to a statistically significant degree.

41. Despite the fact that valproate is a teratogen, Defendants claimed in the product labeling from 1978 until 2006 that any potential increase in birth defects from Depakote, Depakene, and other valproate products was only a possibility, and that the risk was common to the entire class of antiepileptic drugs.

42. Defendants even denied in the product labeling for Depakote, Depakene, and other valproate products that a cause-and-effect relationship between use of valproate and birth defects had been proven, and claimed instead that the increased incidence in birth defects could be attributed to methodological problems in the data, genetic causes, or to risks arising from the epileptic condition itself.

43. In addition to fetal malformations, valproate also increases the incidence of behavioral and cognitive dysfunction, such as lower IQ, attention deficit, and neurodevelopmental delay, in comparison to other anti-seizure medications or no use of medication.

44. Valproate also causes an increased incidence of autism in comparison to other anti-seizure medications or no use of medication.

45. Defendants provided no warning of these behavioral and cognitive risks to Plaintiff BRIANNA ROSE's mother at the time she ingested Depakote during her pregnancy.

46. In fact, Defendants did not warn of a risk of cognitive impairment until a label change in 2011. Even then, Defendants still did not warn that Depakote should be a drug of last resort or completely contraindicated in women of childbearing potential.

47. On July 15, 2013, Abbvie issued a Dear Doctor Letter entitled "**Important Drug Warning,**" in which Abbvie announced major safety labeling changes for Depakote, Depakene and other valproate products.

48. In particular, Abbvie announced "**Changes to Boxed Warning,**" as well as "**Important Limitations of Use in Women of Childbearing Potential**" and "**Pregnancy Category X for Prophylaxis of Migraine Headaches**" for all valproate products.

49. As part of the label change, Abbvie strengthened and clarified the **BLACK BOX** warning in regard to teratogenicity as follows:

> **Fetal Risk**
>
> Valproate can cause major congenital malformations, particularly neural tube defects (e.g., spina bifida). In addition, valproate can cause decreased IQ scores following in utero exposure.
>
> Depakote and Depakote ER are therefore contraindicated in pregnant women treated for prophylaxis of migraine. Valproate should only be used to treat pregnant women with epilepsy or bipolar disorder if other medications have failed to control their symptoms or are otherwise unacceptable.
>
> Depakote Sprinkle Capsules should only be used to treat pregnant women with epilepsy if other medications have failed to control their symptoms or are otherwise unacceptable.
>
> Valproate should not be administered to a woman of childbearing potential unless the drug is essential to the management of her medical condition. This is especially important when valproate use is considered for a condition not usually associated with permanent injury or death (e.g. migraine). Women should use effective contraception while using valproate.

50. As a result of this warning, Depakote, Depakene and other valproate products are labeled as **Category X** for pregnancy for the indication of migraine. They remain **Category D** for bipolar disorder and seizure disorder, but may only be used in pregnancy as drugs of last resort.

51. In addition Defendants revised the **WARNINGS AND PRECAUTIONS** sections in the labels of Depakote, Depakene, and other valproate products as follows:

Birth Defects

- Valproate can cause fetal harm when administered to a pregnant woman. Pregnancy registry data show that maternal valproate use can cause neural tube defects and other structural abnormalities (e.g., craniofacial defects, cardiovascular malformations and malformations involving various body systems). The rate of congenital malformations among babies born to mothers using valproate is about four times higher than the rate among babies born to epileptic mothers using other anti-seizure monotherapies. Evidence suggests that folic acid supplementation prior to conception and during the first trimester of pregnancy decreases the risk for congenital neural tube defects in the general population.

Decreased IQ Following *in utero* Exposure

- Valproate can cause decreased IQ scores following *in utero* exposure. Published epidemiological studies have indicated that children exposed to valproate *in utero* have lower cognitive test scores than children exposed *in utero* to either another antiepileptic drug or to no antiepileptic drugs. The largest of these studies is a prospective cohort study conducted in the United States and United Kingdom that found that children with prenatal exposure to valproate (n=62) had lower IQ scores at age 6 (97 [95% C.I. 94-101]) than children with prenatal exposure to the other antiepileptic drug monotherapy treatments evaluated: lamotrigine (108 [95% C.I. 105–110]), carbamazepine (105 [95% C.I. 102–108]), and phenytoin (108 [95% C.I. 104–112]). It is not known when during pregnancy cognitive effects in valproate-exposed children occur. Because the women in this study were exposed to antiepileptic drugs throughout pregnancy, whether the risk for decreased IQ was related to a particular time period during pregnancy could not be assessed.

- Although all of the available studies have methodological limitations, the weight of the evidence supports the conclusion that valproate exposure *in utero* can cause decreased IQ in children.

- In animal studies, offspring with prenatal exposure to valproate had malformations similar to those seen in humans and demonstrated neurobehavioral deficits.

- Valproate is contraindicated during pregnancy in women being treated for prophylaxis of migraine headaches. Women with epilepsy or bipolar disorder who are pregnant or who plan to become pregnant should not be treated with valproate unless other treatments have failed to provide adequate symptom control or are otherwise unacceptable. In such women, the benefits of treatment with valproate may still outweigh the risks.

Use in Women of Childbearing Potential

- …It is not known whether the risk of neural tube defects or decreased IQ in the offspring of women receiving valproate is reduced by folic acid supplementation. Dietary folic acid supplementation both prior to conception and during pregnancy should be routinely recommended for patients using valproate.

52. Thus Defendants waited 30 years to warn that Depakote is a drug of last resort during pregnancy, and that it is completely contraindicated during pregnancy for the treatment of migraine.

53. However, other less hazardous anti-seizure drugs have included this warning since the early 1980's, including Defendant's own anti-seizure drugs, trimethadione (Tridione) and paramethadione (Paradion), which contained a **BLACK BOX** warning stating,

> **"BECAUSE OF ITS POTENTIAL TO PRODUCE FETAL MALFORMATIONS AND SERIOUS SIDE EFFECTS, [drug name] SHOULD ONLY BE UTILIZED WHEN OTHER LESS TOXIC DRUGS HAVE BEEN FOUND INEFFECTIVE…"**

54. Many other anti-seizure drugs approved prior to 1995 clearly warned that due to potential serious side effects, they should be prescribed only when patients' conditions had proven refractory to treatment with other drugs. Examples include:

> 1) phenacemide (Phenurone) - indicated only for seizures "refractory to other drugs" or when "other available antiepileptics have been found to be ineffective in satisfactorily controlling seizures;"

2) mephenytoin (Mesantoin) - indicated for seizures "in those patients who have been refractory to less toxic anticonvulsants"; "should be used only after safer anticonvulsants have been given an adequate trial and have failed;"

3) methsuximide (Celontin) - indicated for control of absence (petit mal) seizures that are refractory to other drugs;"; and,

4) felbamate (Felbatol) - "recommended for use only in those patients who respond inadequately to alternative treatments".

55. Yet not until 2013 did Defendants revise the labels for Depakote and other valproate products to warn that they should not be a first line medication during pregnancy for treatment of seizure disorder.

56. Defendants failed to warn for over thirty years that valproate should be completely contraindicated and/or a drug of last resort during pregnancy because Defendants sought to exploit the marketing potential for valproate products, and did not want to risk secondary status for the marketing segment of women of childbearing years. In particular, Defendants fought to maintain market share during the three decades that valproate in its various formulations had no generic competition, heedless of the risk of teratogenicity when prescribed to women of childbearing years.

57. With an adequate warning, Plaintiff's mother and her physicians would have pursued a safer, more practical, alternative treatment option to treat her seizure disorder, including but not limited to ethotoin (Peganone) and levetiracetam (Keppra), both of which pose much less risk of teratogenicity with comparable or better efficacy.

58. Moreover, had Plaintiff's mother been warned of the increased risk posed by higher doses of valproate, she would have exercised other treatment options.

59. Plaintiff BRIANNA ROSE was born on October 9, 1997. Since then, Plaintiff has been diagnosed with severe cognitive and behavioral abnormalities.

60. Plaintiff's behavioral and cognitive impairments include: Asperger's Syndrome, OCD, ADHD, low verbal skills, anxiety disorder, developmental delays, emotional outbursts, and impaired coping and social skills. Plaintiff receives medication for her anxiety disorder, Asperger's Syndrome and OCD. As a result of Plaintiff's impairments, she has received individualized therapy and a behavior intervention plan. Plaintiff will continue to require these services and treatment in the future.

FIRST CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(NEGLIGENCE)

61. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

62. Defendants had a duty to exercise reasonable care in the manufacture, design, distribution, marketing, labeling and sale of Depakote, including a duty to ensure that Depakote did not pose a significantly increased risk of bodily harm and adverse events.

63. Defendants failed to exercise ordinary care in the design, formulation, manufacture, design, distribution, marketing, labeling and sale of Depakote in that Defendants knew, or should have known, that their products caused such significant bodily harm or death and was not safe for use by consumers.

64. Defendants also failed to exercise ordinary care in the labeling of Depakote, and failed to issue to consumers and/or their health care provider's adequate warnings of the

increased risk of serious bodily injury or death due to the use of Depakote as compared to other alternative treatments.

65. Despite the fact that Defendants knew or should have known that Depakote posed a serious and increased risk of bodily harm to consumers, Defendants continued to manufacture and market Depakote for use by consumers, including women of childbearing years, and continued to knowingly withhold critical safety information, such as the increased risk at higher doses, the increased risk compared to other treatment options, the increased risk compared to no treatment for seizures, and the increased risk of cognitive and neuropsychological disorders. Further Defendants failed to warn that Depakote should either be completely contraindicated during pregnancy or used only when all other treatment options had proven ineffective in controlling seizures.

66. Defendants knew or should have known that consumers, would foreseeably ingest Depakote during pregnancy and that their children would suffer injury as a result of Defendants' failure to exercise reasonable care as described above.

67. As a direct and proximate result of Defendants' negligence and/or the failure to comply with applicable federal requirements, Plaintiff suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

68. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless

indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

69. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SECOND CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(STRICT PRODUCTS LIABILITY)

70. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

71. Defendants are the manufacturers, designers, marketers, distributors and sellers of Depakote.

72. The Depakote manufactured, designed, marketed, distributed and sold by Defendants was expected to and did reach consumers, without any alterations or changes.

73. The Depakote manufactured, designed, marketed, distributed and sold by Defendants was defective in design or formulation, because when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation.

74. The Depakote manufactured, designed, marketed, distributed and sold by Defendants was defective in design or formulation, because when it left the hands of the Defendants, it was more dangerous than an ordinary consumer would expect.

75. The foreseeable risks of Depakote include an increase in the occurrence of major congenital malformations from fetal exposure to Depakote, the magnitude of which is dramatic in terms of the number of women exposed, the incidence rate, and the devastating nature of resulting harm to the fetus.

76. The fact that harm such as that suffered by Plaintiff will occur from use of Depakote by women of childbearing age is completely foreseeable because (1) Depakote is a known teratogen; (2) Defendants have not prohibited Depakote's use in women of childbearing years; (3) Defendants did not warn against use during pregnancy or limit its use to a drug of last resort; and (4) half of all pregnancies in the United States are unplanned, and few contraception measures are 100% effective.

77. The likelihood that fetal death and injury would result from maternal use of Depakote is very high, based upon relative risk estimates of 6 or more, and studies confirming an incidence rate for major malformations of greater than 30% for infants born of women ingesting higher dosages of valproate.

78. Depakote as manufactured, designed, marketed, distributed, and sold by Defendants is much more dangerous than an ordinary consumer would expect, as maternal use of Depakote during fetal development creates a very high risk of fetal death or major congenital malformations, as well as cognitive, developmental, neurological and behavioral dysfunction.

79. At the time Defendants manufactured, designed, marketed, distributed, and sold Depakote to Plaintiff BRIANNA ROSE's mother, safer, more practical, alternative treatment options were available to treat her seizure disorder, including but not limited to prescription drug alternatives such as ethotoin (Peganone) and levetiracetam (Keppra), both of which pose less risk of teratogenicity with comparable or better efficacy.

80. The Depakote manufactured, designed, marketed, distributed, and sold by Defendants was not unavoidably unsafe, as alternative formulations for anti-seizure medications were available with comparable or better efficacy that did not pose the same teratogenic risk.

81. Moreover, the Depakote manufactured, designed, marketed, distributed, and sold by Defendants was not unavoidably unsafe, because no use of any anti-seizure medication during pregnancy is safer than use of Depakote, and thus the teratogenic risks of Depakote could be avoided entirely during pregnancy.

82. Based upon the foregoing, the Depakote manufactured, designed, marketed, distributed and sold by Defendants was defective in design at the time it left the Defendants' control.

83. As a direct and proximate result of the defective design of Depakote consumed by Plaintiff's mother and/or the Defendants' failure to comply with applicable federal requirements, Plaintiff BRIANNA ROSE suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

84. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

85. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

THIRD CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

86. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

87. Defendants expressly warranted that the relationship between Depakote and birth defects "cannot be regarded as a cause-and-effect relationship."

88. The Depakote manufactured and sold by Defendants did not conform to this express representation because Depakote clearly is a human teratogen when taken in the recommended dosages.

89. As a direct and proximate result of Defendants' breach of express warranty and/or the failure to comply with applicable federal requirements, Plaintiff suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

90. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

91. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FOURTH CAUSE OF ACTION
AS AGAINST THE DEFENDANTS
(BREACH OF IMPLIED WARRANTIES)

92. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

93. At the time Defendants manufactured, marketed, sold, distributed, and/or supplied Depakote, Defendants impliedly warranted that the Depakote was just as safe for the treatment of seizure disorder during pregnancy as any other drugs in the anti-seizure class.

94. At the time Defendants manufactured, marketed, sold, distributed, and/or supplied Depakote, Defendants knew or should have known that treatment of seizure disorders during pregnancy was within the ordinary purpose for which Depakote was to be used.

95. Defendants impliedly warranted Depakote to be merchantable and safe for such use during pregnancy by claiming that the teratogenicity risks of Depakote were presumed to be the same as with other anti-seizure medications, when in fact the risks with Depakote were substantially greater.

96. Contrary to these implied warranties of merchantability, Depakote was not of merchantable quality or safe for its intended use during pregnancy, because Depakote is unreasonably dangerous as described herein.

97. As a direct and proximate result of Defendants' breach of implied warranty of merchantability and failure to comply with applicable federal requirements, Plaintiff suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of

enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

98. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

99. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FIFTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT MISREPRESENTATION)

100. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

101. Defendants manufacture, design, market, label, distribute, and sell Depakote.

102. Defendants have a duty not to deceive consumers and their physicians, including Plaintiff's mother, about Depakote.

103. Defendants made representations to Plaintiff's mother and her physicians regarding the character and/or quality of Depakote for guidance in their decision to select Depakote for her use.

104. Specifically, Defendants represented that their products were just as safe or even safer than other prescription drugs for treatment of seizure disorder available on the market.

105. Defendants knew or should have known that such statements were false.

106. Defendants stated that any risk of teratogenicity with Depakote was a class-wide risk common to anti-seizure medications in general.

107. Defendants knew or should have known that this statement was false, and that Depakote posed a dramatically increased risk of teratogenicity compared to other anti-seizure drugs.

108. Further, Defendants denied that the relationship between Depakote and birth defects was causal, and instead claimed that the association between Depakote and birth defects in the medical literature arose from intrinsic methodological problems, and that genetic risks and the risks posed by epilepsy itself were of greater teratogenicity concern than Depakote.

109. Defendants knew or should have known that these statements were false, and that the relationship between Depakote and birth defects was causal, and that genetic factors and epilepsy itself did not create a greater risk of teratogenicity than Depakote.

110. Defendants had actual or constructive knowledge based upon studies, published reports, and clinical experience of the dangerous teratogenic effects of Depakote, and of the fact that these risks were substantially greater than risks associated with other anti-seizure treatments or no treatment at all.

111. Defendants negligently and/or intentionally misrepresented this information in Depakote's labeling, promotions and advertisements, in order to avoid losses and maximize profits in their sales to consumers and instead labeled, promoted, and advertised their product as being just as safe and effective as other anti-seizure medications.

112. In supplying this false information, Defendants failed to exercise reasonable care or competence in obtaining safety information concerning Depakote and in communicating this information to their intended recipients, including Plaintiff's mother and her physicians.

113. Defendants had a duty to disclose to Plaintiff's mother and her physicians, as well as to the public, that Depakote was not safe for use by women of childbearing years due to its teratogenic effects, or should only be used when all other treatment options had proven ineffective.

114. Defendants also had a duty to disclose the dose-response relationship between Depakote and birth defects and the increased risk of cognitive deficits, neurodevelopmental delay, behavioral disorders, autism and autistic spectrum disorder caused by use of Depakote.

115. Defendants did not disclose any of the above information.

116. Plaintiff's mother and her physicians reasonably relied to Plaintiff's detriment upon Defendants' misrepresentations and/or omissions concerning the serious risks posed by Depakote in the products labeling, advertisements and promotions. Plaintiff's mother and her physicians reasonably relied to her detriment upon Defendants' representations that Depakote was just as safe and effective as other methods of treating and preventing seizures, or just as safe as no treatment of seizures during pregnancy.

117. Defendants' representations that Defendants' labeling, advertisements and promotions fully and accurately described all known risks of the product were false.

118. Had Plaintiff's mother or her physicians known of Defendants' concealment of the true facts—that Depakote was more dangerous for use by women of childbearing years than other anti-seizure medications or no use of anti-seizure medications—Plaintiff's mother would not have been prescribed or used Depakote.

119. As a direct and proximate result of Defendants' negligent or intentional misrepresentations and/or the failure to comply with applicable federal requirements, Plaintiff suffered damages, including but not limited to personal injury, bodily harm, emotional distress,

pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

120. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

121. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SIXTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUDULENT CONCEALMENT)

122. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

123. Defendants misrepresented the soundness and reliability of Depakote to potential users of Depakote through promotional and marketing campaigns. Defendants misrepresented that Depakote was safe and/or effective when used as instructed, when, in fact, it was dangerous to human health. Defendants continued these misrepresentations for an extended period of time, without disclosing material information.

124. At the time Defendants promoted Depakote as safe and/or effective, Defendants did not have adequate proof upon which to base such representations and, in fact, knew or should have known that the drug was dangerous.

125. Defendants concealed these design and manufacturing defects by withholding information pertaining to inherent design, manufacturing, and safety defects and high risks of severe birth defects as described herein, and instead presented Depakote as safe and reliable.

126. Defendants intentional misrepresentations and omissions were made willfully, wantonly or recklessly to induce the purchase of Depakote.

127. Defendants knew that Plaintiff's mother, and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding Depakote, as set forth herein.

128. Plaintiff's mother, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

129. As a result of the foregoing acts and omissions, the Plaintiff suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

130. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (NEGLIGENT MISREPRESENTATION)

131. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

132. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff's mother, the FDA and the public in general that said product, Depakote, had been tested and found to be safe for the treatment of seizures.

133. The representations made by Defendants were, in fact, false.

134. Defendants failed to exercise ordinary care in the representation of Depakote, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendants negligently misrepresented Depakote's high risk for use by women of childbearing years due to its teratogenic effects.

135. Defendants breached their duty in representing Depakote's serious teratogenic effects to the medical and healthcare community, to the Plaintiff's mother, the FDA and the public in general.

136. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, so as to warrant the imposition of punitive damages.

137. As a result of the foregoing acts and omissions, the Plaintiff suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering,

permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

138. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

EIGHTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUD AND DECEIT)

139. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

140. Defendants conducted research and used Depakote as part of their research.

141. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff's mother, doctors, hospitals, healthcare professionals, and/or the FDA that Depakote was safe and effective for the treatment of seizures.

142. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff's mother.

143. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff's mother, as well as respective healthcare providers and/or the FDA.

144. The information distributed to the public, the FDA, and the Plaintiff's mother by Defendants, including but not limited to reports, press releases, advertising campaigns, television

commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

145. The information distributed to the public, the FDA, and the Plaintiff's mother, by Defendants intentionally included representations that Defendants' drug Depakote carried the same teratogenic risks, hazards, and/or dangers as other antiepileptic drugs.

146. These representations were all false and misleading.

147. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that Depakote was not as safe as other prescription drugs for treatment of seizure disorder available on the market.

148. Defendants intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff's mother, regarding the safety of Depakote, specifically but not limited to Depakote being just as safe or even safer than other prescription drugs for treatment of seizure disorder available on the market.

149. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff's mother, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff's mother, to falsely ensure the quality and fitness for use of Depakote and induce the public, and/or the Plaintiff's mother to purchase, request, dispense, prescribe, recommend, and/or continue to use Depakote during pregnancy.

150. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff's mother that Depakote was fit and safe for use as treatment of seizures.

151. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff's mother that Depakote was fit and safe for use as an anti-seizure medication and just as safe or even safer than other prescription drugs for treatment of seizure disorder available on the market.

152. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff's mother that Depakote did not have an increased risk of teratogenicity compared to other anti-seizure drugs.

153. That these representations and others made Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

154. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff's mother, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff's mother and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff's mother to purchase, use, rely on, request, dispense, recommend, and/or prescribe Depakote.

155. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Depakote to the public at large, the Plaintiff's mother in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of seizure treatment.

156. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of Depakote by concealing and suppressing material facts regarding the dangerous and serious teratogenic concerns of Depakote.

157. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff's mother, as well as her respective healthcare professionals into a sense of security so that Plaintiff's mother would rely on the representations and purchase, use and rely on Depakote and/or that Plaintiff's mother's respective healthcare providers would dispense, prescribe, and/or recommend the same.

158. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff's mother, as well as her respective healthcare professionals would rely upon the information being disseminated.

159. Defendants utilized direct to consumer adverting to market, promote, and/or advertise Depakote.

160. That the Plaintiff's mother and/or her respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of seizure treatment and were thereby induced to purchase, use and rely on Defendants' drug Depakote.

161. That at the time the representations were made, the Plaintiff's mother and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious teratogenic concerns of Depakote.

162. That the Plaintiff's mother did not discover the true facts with respect to the dangerous and serious teratogenic concerns, and the false representations of Defendants, nor could the Plaintiff's mother with reasonable diligence have discovered the true facts.

163. That had the Plaintiff's mother known the true facts with respect to the dangerous and serious teratogenic concerns of Depakote, the Plaintiff's mother would not have purchased, used and/or relied on Defendants' drug Depakote.

164. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff's mother.

165. As a result of the foregoing acts and omissions, the Plaintiff suffered damages, including but not limited to personal injury, bodily harm, emotional distress, pain and suffering, permanent physical, mental, neurologic, cognitive and behavioral injuries, loss of enjoyment of life, economic and non-economic damages, and will continue to suffer such injuries, distress, pain and suffering, harm, damages, and economic loss in the future.

166. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the

safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

3. Awarding all applicable statutory damages of the state whose laws will govern this action;

4. Awarding Plaintiff's reasonable attorneys' fees;

5. Awarding Plaintiff's the costs of these proceedings; and

6. Such other and further relief as this Court deems just and proper.

Dated: October 6, 2017

Respectfully submitted,

SCHLICHTER BOGARD & DENTON LLP

By: /s/ Roger C. Denton

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

/s/ Roger C. Denton